IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S):	Wermeling	CONF. NO.:	5461
SERIAL NO.:	10/803,521	GROUP NO.:	1617
FILING DATE:	March 17, 2004	EXAMINER:	Yu, Gina C
TITLE:	Intranasal Benzodiazepine Compositions		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF DANIEL P. WERMELING, PHARM.D., FASHP, FCCP., UNDER 37 CFR 1.132

I, Daniel P. Wermeling, Pharm.D, FASHP, FCCP, hereby declare as follows:

1. I am a Professor in the Pharmacy Practice and Science Department at the University of Kentucky. I have worked in the field of drug formulations and delivery for over 20 years and have numerous publications in this field. Attached is a copy of my curriculum vitae as Exhibit A.

2. I am the named inventor of the subject matter claimed in the above-identified patent application.

3. I have reviewed the pending patent application, the pending claims, and the Office Action mailed May 9, 2008 in which various claims stand rejected under 35 U.S.C. § 103 as being unpatentable over certain combinations of U.S. Patent No. 5,166,202 to Schweizer (hereinafter "Schweizer"), Hjortkjaer *et al.* in *J. Pharm. Pharmacol.* 1999, 51: 377-383 (hereinafter "Hjortkjaer"), U.S. Patent No. 6,565,832 to Haslwanter (hereinafter "Haslwanter"), U.S. Patent No. 5,554,639 to Craig (hereinafter "Craig"), Fisgin *et al.* (2000) J. Child Neurol. 15: 833-835 (hereinafter "Fisgin"), U.S. Patent No. 5,789,375 to Mukae (hereinafter "Mukae"), and Knoester *et al.* (2002) Br. J. Clinc. Pharmacol. 53:501-507 (hereinafter "Knoester").

4. I am providing the following information in support of our position that neither Schweizer Hjortkjaer, Haslwanter, Craig, Fisgin, Mukae, nor Knoester render obvious the subject matter of claim 11.

5. In my experience, the T_{max} of midazolam administered intranasally can be affected by the components included in the intranasal pharmaceutical composition. For example, in my experience, certain components can increase the solubility of midazolam in the intranasal pharmaceutical composition in order to deliver a more concentrated form of midazolam. This, in turn, can affect T_{max}. Further, in my experience, certain components can affect the nature of the spray (e.g., droplette size and spray plume geometry), which can affect T_{max}. For example, in my experience, polyethylene glycol and propylene glycol can affect the viscosity of a liquid midazolam formulation, which affects the nature of the spray. It is my experience that variables, such as these, make it difficult to predict the T_{max} for intranasal delivery of midazolam using certain intranasal pharmaceutical compositions.

6. Further, based on my review of the art cited in the Office action, in my opinion these documents do not provide guidance on how polyethylene glycol and propylene glycol will effect the T_{max} of a midazolam formulation. Further, in my opinion, the art cited in the Office action does not provide enough guidance to permit one of skill in the art at the time the invention was made to reasonably predict the T_{max} for the midazolam pharmaceutical composition of claim 11, as amended.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of this application or any patent issuing therefrom.

Dated: November 7, 2008

Daniel P. Wermeling, Pharm.D., FASHP, FCCP

EXHIBIT A

CURRICULUM VITAE FOR DANIEL P. WERMELING

I. GENERAL INFORMATION

Address: 201 D College of Pharmacy
University of Kentucky
725 Rose Street
Lexington, KY 40536-0082

Telephone: (859) 323-7499
Fax: (859) 257-9838

Email: dwermel@uky.edu

Certificate of Specialty Licensure: Registered Pharmacist
State of Kentucky - 1983
Pharmacy License #8933

II. EDUCATION

Fellowship: 1985-87
Drug Product Evaluation Unit
College of Pharmacy
University of Kentucky
Lexington, Kentucky

Residency: 1983-85
University Hospital
Albert B. Chandler Medical Center
University of Kentucky
Lexington, Kentucky

Doctor of Pharmacy: 1977-83
College of Pharmacy
University of Kentucky
Lexington, Kentucky

III. PROFESSIONAL EXPERIENCE

Associate Professor (with tenure)
College of Pharmacy, University of Kentucky
1998 – Present

Chief Scientist
Intranasal Therapeutics, Inc.
2004-2006

Senior Vice President and Chief Operating Officer
Intranasal Technology, Inc.

2002 – 2004 (unpaid leave of absence)

Scientific Director, Kentucky Center for Clinical Research & Investigator Services,
University of Kentucky Medical Center
1997 – 2000

Director, Investigational Drug Service
Department of Pharmacy
A B Chandler Medical Center
1990 – 2000

Associate Research Professor and Director
Drug Product Evaluation Unit
Center for Pharmaceutical Science and Technology
College of Pharmacy, University of Kentucky
1994 – 1998

Assistant Research Professor and Director
Drug Product Evaluation Unit
Center for Pharmaceutical Science and Technology
College of Pharmacy, University of Kentucky
1990 – 1994

Clinical Research Associate
Merrell Dow Research Institute
Cincinnati, Ohio
1988 – 1990

Coordinator - Bristol-Myers Industrial Clerkship
Investigational Drug Pharmacist
Assistant Director of Hospital Pharmacy
University of Kentucky Medical Center
1987 – 1988

Research Fellow – Drug Product Evaluation Unit, College of Pharmacy University of Kentucky
1985 – 1987

Pharmacy Resident - University of Kentucky Medical Center
1983 – 1985

IV. ACADEMIC APPOINTMENTS

Associate Professor (with tenure)
Full Member Graduate School Faculty
College of Pharmacy
University of Kentucky
902 Rose Street
Lexington, KY 40536
1998 – Present

Associate Research Professor
Associate Member of the Graduate School Faculty
Division of Pharmacy Practice & Science
College of Pharmacy
University of Kentucky
902 Rose Street
Lexington, KY 40536
1994 – 1998

Assistant Research Professor
Associate Member Graduate School Faculty
Division of Pharmacy Practice & Science
College of Pharmacy
University of Kentucky
907 Rose Street
Lexington, KY 40536
1990 – 1994

V. HOSPITAL OR CLINICAL APPOINTMENTS

Assistant Director of Pharmacy – Obstetrics and Psychiatry
Investigational Drug Pharmacist
University Hospital
Albert B. Chandler Medical Center
Lexington, KY
1987 – 1988

Director, Investigational Drug Service
Department of Pharmacy
University Hospital
Albert B. Chandler Medical Center
Lexington, KY
1990 – 2000

VI. CONSULTING ACTIVITY

Apotex Pharmaceuticals 2007-
Patent Analysis

The Round Table Group 2007-
Drug Development Consulting

Biovail Corporation 2006
Drug Delivery for Pain Management

Boston Life Sciences – 2005–6
Intrathecal Analgesia Delivery

Cydex Corporation – 2005
Nasal Formulation Approach

Intranasal Technology, Inc. 2004 -
Nasal Drug Delivery

Purdue Pharma – 2003 – 2004
Oxycodone Pharmacokinetics & Pharmacodynamics

Intranasal Technology Inc.
1998 – 2001

Pain Care Incorporated
1994 – 1995

NIH Master Agreement for the Clinical Evaluation of
Investigational Anti-Epileptic Drugs - Co-Investigator
1993 – 1999

Health Economics Research
Propofol Pharmacoeconomic Evaluation
1992 – 1994

Hoffman LaRoche Pharmaceuticals
TAT Antagonist - Antiretroviral Pharmacokinetics
1992

Evaluation of Drug Interactions
Chapter 2 Anesthetic Drug Interactions
1988 – 1998

VII. TEACHING ACTIVITY

Graduate Program Teaching

2007-	CME 599/PHR 760 Buccal and Nasal Drug Delivery, 2 contact hours
2004 -	PHR 764 Drug Development Regulation and Clinical Research Methods, Primary Instructor, 3 credit course 26 of 43 contact hours. This is a required course for Clinical and Experimental Therapeutics Ph.D. program students.
2004	PHR 760-009 Introduction to Translational Research (Co-instructor), 2 credit course, 8 contact hours
2001	PHR 760-009 Introduction to Drug Development and Clinical Research – (Primary Instructor)
2001	NIH K-30 Elective Course in Clinical Research

Professional Program Courses Participation

2008-	PHR 924 – The Drug Development Process – 3 contact hours

	2006 - PHR 564 Introduction to FDA & the Drug Development Process – 2 credit hours elective – Primary Instructor
	2006- PHR 946 PY 2 Spring Semester Pain Management Module Leader – 23 contact hours
2004-05	PHR 956-7 Fall Semester, Pain Management Module Leader and Primary Lecturer PY 3 Therapeutics, 23 contact hours
1994-1999	Pharmacy Seminar (PHR 890)
1993-2002	Nervous Systems (PHR 851)
1992-2001	Pharmacy Practice Clerkship (PHR 866)
1991-1999	Advanced Institutional Practice Management (PHR 833)
1991-2001	Independent Problems in Clinical Pharmacy (PHR 895)
1988	Implications of Drug Therapy for Nurses (NUR 866)
1987-1988	Bristol-Myers Industrial Clerkship
1986-1988	Institutional Pharmacy Practice (PHR 880)
1986-1988	Applied Therapeutics I & II (PHR 866-868)
1986-1988	Clinical Orientation Clerkship (PHR 870)

Hospital Pharmacy Residency

Supervise 6-7 pharmacy residents per year (1 – 2 month rotations) who participate in a Clinical Drug Development Rotation. Residents obtain first hand experience in clinical research administration and conduct. 1990 – 1998

Post-Doctoral Fellow Training

Carinda Field, Pharm.D. (fellow)
1991 – 1993
Charles Xie, M.D., Ph.D. (fellow)
1996 – 1997

Graduate Students

Ben Chamberlain, BS, mentor for NIH GCRC mentored student program. 2007-08
Committee Member for Jennifer King, Ph.D., Department of Gerontology 2004-2007
Committee Member for Jennifer Oh, Pharm.D., (thesis masters student and fellow) 2004-06
Mentor for Jodi L. Miller, Pharm.D., M.S. (non-thesis masters student and fellow) 2000 – 2002
Committee Member for Doug Hiser, D.D.S., M.S. (non-thesis masters student in College of Dentistry) 1998 – 1999
Mentor for Lance Piecoro, Pharm.D., M.S. (non-thesis masters student and fellow)
1995 – 1998

VIII. ADVISING ACTIVITY

2 new PYI students per year – 1990-1998

IX. ADMINISTRATIVE ACTIVITY AND UNIVERSITY, STATE AND NATIONAL SERVICE

College of Pharmacy Committees

Appointment, Promotion and Tenure 2005 - 2008
Graduate Education and Research Committee 2006 - 2008
Practice Plan Committee 2005 -
Advisor to Associate Dean for Research on Clinical Research 2004-
College of Pharmacy Executive Committee, 2000 – 2001
Nominations Committee, 1999 –2001
College Practice Plan Committee, 1997 – 1999
PPS Division Practice Plan Expenditure Committee, 1997 – 1999
Clinical Pharmacology Oversight Committee, 1994 – 1999
Division Research/Computer Equipment Committee, 1993 – 1997
Co-Advisor Pre-pharmacy Club, 1994 – 1996
Co-Advisor Pre-pharmacy Club, 1994 – 1996
Residency and Seminar Committee, 1990 – 1991
Student Advisor Committee, 1984 – 1985
Curriculum Committee, 1983 – 1985

Hospital Committees

Corporate Compliance Committee 1999-2000
Research Subcommittee, 1999 – 2000
Integrated Clinical Information System, 1998 – 1999
Clinical Research Reengineering Task Force, 1995 – 1997
Health Enterprise Research Information Committee, 1997
Residency Research Committee, 1995 – 2000
Resident Advisor Committee, 1990 – 1991
Resident Advisor Committee, 1990 – 1991
Obstetric Service Task Force, 1987 – 1988
Resident Advisor Committee, 1985 – 1987
Pharmacy Computer Search Committee, 1985 – 1986

College of Medicine Committees

NIH Center for Clinical and Translational Research, University of Kentucky Medical Center, 2008-
NIH General Clinical Research Center Scientific Advisory Committee 2005 - 2008
NIH General Clinical Research Center/Advisory Committee, 1996 – 2001
NIH General Clinical Research Center/Drug Product Evaluation Unit Space Committee, 1993 – 2001
NIH General Clinical Research Center/Drug Product Evaluation Unit Operations Subcommittee, 1993 – 2001

University Committees

Clinical Research Task Force – 2004 - 2006
Institutional Biosafety Committee – Ex-Officio, 1998 – 2000
KCCRIS Advisory Committee – Ex-Officio, 1997 – 2000
Research Process Planning Committee, 1997 – 2000

Medical Institutional Review Board – Ex-Officio Member, 1993 – 2000

Commonwealth of Kentucky

Kentucky Life Science Organization – State science and development leaders advising the Governor on life science economic development policy, 2004 - 2007

KLSO Executive Committee and Founding Board Member, 2004 - 2007

National Committees

American College of Clinical Pharmacy – Blue Ribbon Task Force on Pharmacometrics. 2008-2009

American College of Clinical Pharmacy, Research Affairs Committee, Chair, Sub-committee on national pharmacy practice based research networks. 2007-08

National Institutes of Health, Gene and Drug Delivery Systems Study Section for SBIR/STTR Grants, July 10, 2006

National Institutes of Health, Gene and Drug Delivery Systems Study Section for SBIR/STTR Grants, November 28, 2005.

National Institutes of Health, Gene and Drug Delivery Systems Study Section Review Committee, November 17-18 2005

American College of Clinical Pharmacy, Task Force on Research in Special Populations, 2005-6

American College of Clinical Pharmacy, Research Committee, 1998 – 1999

American Society of Health-System Pharmacists, PALS Program, 1997 – 1999

American Society of Health-System Pharmacists, Council on Professional Affairs, 1996/97 & 1997/98 & 1998/99

University Health System Consortium Benchmarking Committee, 1997 – 1999

American Society of Health-System Pharmacists, Facilitator – Section of Clinical Specialists – Investigational Drugs and Clinical Research, 1995 – 1997

American College of Clinical Pharmacy, Credentials Committee, 1995
Chair, 1996-1997, 1997 – 1998
Chairman, 1995 – 1996

American College of Clinical Pharmacy, Women's Health Care PRN
Chairman Elect, 1994 – 1995

American College of Clinical Pharmacy, Special Task Force on Women's Health & Education Issues, 1991 – 1993
Vice Chairman, 1993 – 1994

American College of Clinical Pharmacy, Research Affairs Committee, 1991 – 1992, Vice Chairman, 1992 – 1993

American Society of Hospital Pharmacists Nominee for Position on FDA OTC Drug Advisory Committee, October 1991

Liaison, University Health-System Consortium Clinical Research & Investigator Services, 1990 – 1999

ASHP Drug Therapy Research Awards Program Selection Panel, 1999 – 2000

X. SPECIAL ASSIGNMENTS

Senator – University of Kentucky 2008-2011

University of Kentucky Human Gene Therapy Task Force, 1998 – 1999

Special Assistant to the Dean, 1999-2001

XI. HONORS

Recipient, American College of Clinical Pharmacy Research Institute Award, 2007

Fellow, American College of Clinical Pharmacy (FCCP), October 2006

Kentucky Colonel, from Governor Ernie Fletcher, for research entrepreneurship in the Commonwealth of Kentucky, January 2006

Fellow, American Society of Health System Pharmacy (FASHP), June, 1998

Kentucky Society of Hospital Pharmacists
Research Pharmacist of the Year, 1988

XII. PROFESSIONAL ACTIVITY AND PUBLIC SERVICE

Organizations

American College of Clinical Pharmacology 2008-
American College of Clinical Pharmacy 1990-
Kentucky Society of Hospital Pharmacy 1990 -
Phi Delta Chi (Pharmaceutical Fraternity) 1990-94
American Pharmaceutical Association 1990 - 2000
American Society of Health-System Pharmacy 1983-
Society of Research Administrators – 1990-97
American College of Research Professionals – 1994-97
Drug Information Association – 1994-97
American Association of Pharmaceutical Scientists 2000-

Journal Reviewer

Epilepsy Research 2008
BMC Pharmacology 2008
Expert Opinion on Pharmacotherapy 2008 x2
Journal of Pharmacy Practice and Research 2008
Pharmacotherapy 2008
Drug Benefit Trends 2007
The Journal of Pain 2007
Yonsei Medical Journals 2007
Expert Opinion in Drug Discovery 2007
Pharmacotherapy 2007
Biopharmaceutics and Drug Disposition 2007
Journal of Clinical Anesthesia 2006
BMC Clinical Pharmacology 2006
Pharmacotherapy – 2006
Johns Hopkins Advanced Studies in Medicine 2006
Journal of Pharmacy and Pharmacology 2006
Drugs of Today 2006
Drug Profiles 2006
Journal of the American Board of Family Practice 2005 -
The Annals of Pharmacotherapy – 1987-
American Journal of Hospital Pharmacy 1987-
Drug Intelligence and Clinical Pharmacy 1987- 1995
The Journal of Pharmacy Technology 1990-91
Journal of Pharmaceutical Sciences – 1990-91

Reviewer of Proposals

ACCP Women's Education Foundation – Foundation Awards Program Selection Panel 1997-2000
ASHP Foundation Award – Innovative Clinical Pharmacy Research – 1997-2000

Reviewer of Abstracts

For ACCP for publication in Journal of Pharmacology, Pharmacotherapy 1991-2001, 2004 –

XIII. INVITED SPEAKING ENGAGEMENTS

International

2008 International Nasal Drug Delivery 2008. "Intranasal Delivery of Analgesic Compounds: Experience with Hydromorphone in Acute Trauma Pain. April 8th, 2008, London, UK

2008 New Horizons in the Development of Antiepileptic Drugs: Non-traditional Approaches to Treat Epilepsy Conference. "Intranasal Delivery of Anti-epileptic Medications". March 7, 2008, Dublin, Ireland

2007 10th Annual Nasal Drug Delivery Conference. "Where is Nasal Delivery Research Headed? " February 8, 2007, London, UK.

2006 Biovail Pain Management Forum. "Drug Delivery Approaches Employed in Pain Management Pharmacotherapy." December 15, 2006. New York, NY.

2005 ATACCC 2005 Conference – Advanced Technology for Combat Casualty Care. "Needle-Free, Self-Administered Nasal Hydromorphone for the Rapid Treatment of Moderate to Severe Acute Pain." Sponsored by the Army and Navy Casualty Care Research Programs and the Air Force Surgeon General. Tampa, FL, August 16, 2005

2005 Eighth Annual Anti-epileptic Drug Conference, "Intranasal Delivery of Benzodiazepines for the Treatment of Seizure". March 2005, Biscayne, FL

2004 Practical Approaches to Nasal and Pulmonary Drug Delivery II, "Nasal Delivery of Analgesics for Acute and Break-Through Cancer Pain", Valois Nasal and Pulmonary Delivery Conference, Delray Beach, Florida

2003 Management Forum LTD – Sixth International Conference Exploring the Rapidly Developing Area of Nasal Drug Delivery, "Nasal Drug Delivery Opportunities in Pain Management Therapeutics", London, England

2002 Technology Catalysts – 19th Annual International Technology Transfer Forum, "Nasal Delivery of Medications for the Central Nervous System", Reston, Virginia

2002 Management Forum LTD – Fifth International Conference Exploring the Rapidly Developing Area of Nasal Drug Delivery, "Design of Products for Acute, Subacute, and Chronic CNS Medical Indications", London, England

2001 Strategic Research Institute – 6th International Drug Delivery Technologies and Deal Making Summit, "Nasal Drug Delivery: A Leading Edge Technology for Systemic Delivery", Princeton, New Jersey

National

2007 Medical University of South Carolina. Nasal Drug Delivery of Medications for the Treatment of Alcoholism. January 5, 2007. Charleston, SC.

2006 National Institute of Alcohol Abuse and Alcoholism – Nasal Drug Delivery as an Interventional Approach to Alcohol Drug Therapy, NIH, June 20, 2006, Rockville, MD

2006 University of Chicago College of Medicine – "Nasal Drug Delivery – Pharmacotherapy Option and Research Tool". May 12, 2006, Chicago, Il

2005 American College of Clinical Pharmacy – Spring Research and Practice Meeting, Navigating Research: "Patient Safety, Privacy and Funding Issues", April 7, 2005 Myrtle Beach, SC.

2001 Institute for International Research – Inhalation Technology Conference, "Nasal Drug Delivery: A Leading Edge Technology for Systemic Delivery", Boston, Massachusetts

2001 MedTech Insight, Investment in Innovation – A Preview of Early-Stage Medical Technology Companies, "Nasal Drug Delivery: A Leading Edge Technology Platform for Drug Delivery", New York, New York

2000 American College of Clinical Pharmacy, "Pharmacokinetics (PK) of Intranasal Hydromorphone (HM) in Healthy Subjects", Los Angeles, California

1999 Massachusetts Society of Health-System Pharmacists, "Managing Issues Related to Clinical Research", Boston, Massachusetts

1999 Corporate Compliance and Clinical Research, University Health System Consortium, Chicago, Illinois

1998 Society of Research Administrators, "Addressing the Investment in Clinical Research"

1998 American Society of Health-System Pharmacists, "Is Your Pharmacy Ready for Gene Therapy?"

1997 American Society of Health System Pharmacists Annual Meeting, "Clinical Research: Regulatory Issues"

1996 Society of Research Administrators, "How to Prepare for a Successful FDA Audit for a Clinical Investigator or IRB"

1995 American Society of Health-System Pharmacists, "New NIH and FDA Guidelines Regarding Women's Participation in Clinical Research"

1993 Auburn University, Annual Clinical Practice and Research Forum, "Development of a Clinical Research Unit"

1992 Burroughs Wellcome Company, Inc., "First Time in Man Drug Trials"

1991 American Society of Hospital Pharmacists, "Managing Grant Funds: The University Perspective"

1991 Applied Research Ethics National Association (ARENA), "Handling Equitable Selection"

1991 American College of Clinical Pharmacy, "Women's Participation as Research Subjects"

1988 St. Louis Society of Hospital Pharmacists, "Pharmacy Considerations for Implementing a PCA Program in Your Hospital"

1987 American Society of Hospital Pharmacists, "Evaluation of the Travenol Infusor with Patient Control Module as a PCA Device for Treatment of Postoperative Pain"

1987 Georgia Society of Hospital Pharmacists, "Pharmacy Considerations for Implementing a PCA Program in Your Hospital"

1986 Intravenous Nurses Association of Northwest Florida, "Patient-Controlled Analgesia and the Cancer Patient"

1986 Indiana Society of Hospital Pharmacists, "Patient-Controlled Analgesia: Implementation of a Clinical Service Program"

1986 American Society of Hospital Pharmacists, "Patient-Controlled Analgesia: Implications for Patient Care and Pharmacy Services"

1986 Butorphanol Tartrate Symposium: Research Advances in Multiple Clinical Settings, "Patient-Controlled Analgesia for Postoperative Pain: Streamlining Drug Delivery for Pain Management"

1985 American Society of Hospital Pharmacists. "Patient-Controlled Analgesia: Parallel Development of the Research Tool and Clinical Service Program"

1985 Ohio Conference on Clinical Pharmacy and Clinical Pharmacology, "Patient Controlled Analgesia"

1984 Southeastern Residents Conference, "Pentobarbital Coma in Refractory Cerebral Edema"

1984 American Society of Hospital Pharmacists, "Osmolality of Injectable Drugs in Minibags: Predicted vs. Actual Value"

State

2006 University of Kentucky College of Pharmacy Continuing Education Series, Fall Meeting, October 6, 2006. "Multi-modal, Mechanism Based Approaches to Treatment of Chronic Non-Malignant Pain".

2004 University of Kentucky, Health and Medical Care Delivery Systems – HSM 241, "Intranasal Technology, Inc.: A Leading Edge Specialty Pharmaceuticals Company", Lexington Kentucky

2003 University of Cincinnati, Biotechnology and Pharmaceutical Management Course, "Intranasal Technology, Inc.: A Leading Edge Specialty Pharmaceuticals Company", Cincinnati Ohio

2001 The Entrepreneurship Committee of the Greater Louisville Health Enterprises Network, Life Sciences Investor Forum "Intranasal Technology, Inc. A Leading Edge Drug Delivery Company", Louisville Kentucky

1996 Sanders-Brown Center on Aging, Conference for Pharmacists, "Considerations in Conducting Clinical Trials with Alzheimer's Disease Patients"

1986 Kentucky Pharmacists Association, "Patient-Controlled Analgesia: Implementation of a Clinical Service Program"

1985 Kentucky Pharmacists Association, "New Concepts in Pain Management"

1984 Intravenous Therapy and Nutrition Technology Update for 1984, University of Kentucky College of Pharmacy Continuing Education Program, "Preparing Drugs in the Pharmacy for Patient Administration – Concern for pH, Osmolality, and Drug Concentration"

Local

2008 "The Drug Approval Process". Transylvania University, Lexington, KY Pre-professional Degree Student Forum, May 12, 2008

2007 "Drug Development in the United States". NIH GCRC Mentored Student Lecture Series, July 23, 2007.

2007 "Nasal Drug Delivery for Treatment of Alcoholism". NIH General Clinical Research Center lecture, March 12, 2007.

2006 "Translational Research in Nasal Drug Delivery". Center for Drug and Alcohol Translational Research, University of Kentucky, March 6, 2006

2001 "Making New Drugs in the Bluegrass: Public-Private Partnership" Fasig-Tipton, Lexington Kentucky, Sponsored by the Lexington Rotary Club

2001 Start Up @ 5, Sawyers Downtown, Lexington Kentucky, Sponsored by Kentucky Science and Technology Corporation

2000 "Evolution of Faculty Research into a New Economy Business" Hyatt Regency, Lexington, Kentucky, Sponsored by UK Board of Trustees

1996 Channel 36-TV interview with Sandy Gray, "Making Sense of Medications Today"

1994 Department of Psychiatry Grand Rounds

1994 Investigational Drugs for Treatment of Sepsis at the University of Kentucky Medical Center, Radisson Hotel, Lexington, Kentucky, September 12, 1994

1993 "Drug Development Opportunities: Psychiatric Drug Evaluation"

XIV. PATENTS ISSUED As Primary Inventor

"System and Method for Intranasal Administration of Lorazepam"
Patent No.: US 6,610,271
Date of Patent: August 26, 2003

"Programmable Multi-Dose Intranasal Drug Delivery Device"
Patent No.: US 6,948,492
Date of Patent: September 27, 2005

Submitted / Pending Applications as Primary Inventor

Pharmaceutical Compositions Comprising an Opioid Receptor Antagonist and Methods for Using Same.
US2007/0212307

Intranasal Delivery of Antipsychotic Drugs
WO 2006/023497A2
US20060039869A1

Composition & Methods for Intranasal Delivery of Tricyclic Canabinoids
US-2007-0060639-A1
PCT/US2006/034562

"System and Method for Intranasal Administration of Opioids"
Pub. No.: US 20030077300 A1
Pub. Date: April 24, 2003

"Intranasal Benzodiazepine Compositions "
Pub. No. US 20040176359

"Intranasal Opioid Compositions"
Pub No. US 20040115133

XV. INDs SUBMITTED TO THE FDA

Cimetidine Injection 1991 (SKB contract)

DSPC Liposome 1994 (The Liposome Company contract)

Ondansetron Nasal Spray 1996 (GSK contract)

Hydromorphone Nasal Spray 1998 (Intranasal Technology Inc. contract)

Butorphanol Nasal Spray 1998 (Intranasal Technology Inc. contract)

Lorazepam Nasal Spray 1999 (Intranasal Technology Inc. contract)

Midazolam Nasal Spray 1999 (Intranasal Technology Inc. contract)

Haloperidol Nasal Spray 2000 (Intranasal Technology Inc. contract)

XVII. PEER REVIEWED RESEARCH AND CREATIVE PRODUCTIVITY

Intranasal Delivery of Antiepileptic Medications for the Treatment of Seizures. Wermeling DP. Submitted. Neurotherapeutics

A Pharmacokinetic and Pharmacodynamic Study, in Healthy Volunteers, of a Rapidly Absorbed Intranasal Midazolam Formulation. Wermeling, DP, Record KE, Archer SM, Rudy AC. Submitted. Epilepsy Research

In vitro/In vivo correlation of a 16.0% naltrexone hydrochloride gel in hairless guinea pigs and healthy human volunteers utilizing microneedle array technology. Banks, SL, **Wermeling, DP,** Gill HS, Prausnitz MP, Stinchcomb A. In submission, Pharmaceutical Research

Clinical Research in Special Populations: ACCP White Paper. Accepted, In press, Pharmacotherapy

A Pilot Pharmacokinetic Study of Nasally Delivered Haloperidol Compared to Intravenous and Intramuscular Administration. Wermeling D, Ashford W, Archer S, Rudy A, Miller J. Pharmacotherapy 2008; 28: 875-882.

Microneedles Permit Transdermal Delivery of a Skin-Impermeable Medication to Humans. Wermeling DP, Banks SA, Hudson DA, Gill HS, Prausnitz M, Stinchcomb AS. Proceedings of the National Academy of Sciences 2008, Feb 12, 108: (6) 2058-63.

Intranasal Absorption of Delta 9 tetrahydrocanabinol and WIN 55,212-2mesylate in rats. Valiveti S, Agu RU, Hammell DC, Paudel KS, Earles DC, **Wermeling DP**. Stinchcomb AS. Eur J Pharm Biopharm 2006, Aug 23.

Pharmacokinetics and Pharmacodynamics of a New Intranasal Midazolam Formulation in Healthy Volunteers. Wermeling DP, Record K, Kelly TH, Archer SM, Clinch T, Rudy AC. Anesthesia and Analgesia 103 (2) August 2006

Ziconotide Infusion for Severe Chronic Pain: A Case Series of Patients with Neuropathic Pain. Wermeling DP, Berger JR., Pharmacotherapy 2006: 26 (3), 395-402.

Pharmacokinetics, Bioequivalence and Dose Reproducibility of Intranasal Butorphanol After Administration with Two Different Nasal Spray Pumps. Wermeling DP, Miller JL, Archer SM, Rayens MK, Rudy AC., Journal of Clinical Pharmacology August 2005; 45 (8): 969-73.

A Review of Ziconotide, an N-Type Calcium Channel Antagonist, Delivered by Intrathecal Adminsitration for the Treatment of Chronic Pain. Wermeling, DP. Pharmacotherapy 2005: 25 (8) 1084-94.

A Randomized, Double-Blind, Parallel-Group Study Comparing the Analgesic Effects of Intranasal Butorphanol Tartrate to Placebo, Using a Unit Dose Nasal Spray Device, in the Dental Impaction Pain Model. Wermeling, DP, Grant GM, Lee A, Alexander N, Rudy AC. Clinical Therapeutics 2005; 27 (4): 430-440.

Bioavailability of Intranasal Butorphanol Administered from a Single-dose Sprayer. Davis GA, Rudy A, Archer SM, **Wermeling, DP**. American Journal of Health System Pharmacy 2005 62 (1): 48-53

A Multiple Dose Phase 1 Study of Intranasal Hydromorphone Hydrochloride in Healthy Volunteers. Rudy AC, Coda BA Archer SM, **Wermeling DP**. Anesth Analg 2004 99 (5): 1379-86.

Bioavailability of Intranasal Butorphanol Using Unit-Dose Spray Pump in Healthy Volunteers. Davis GA, Rudy AC, Archer SM, Wermeling DP. Am J Health Syst Pharm 2004; 62; Jan 1, 48-53

Bioavailability and Pharmacokinetics of Intranasal Hydromorphone in Patients With Allergic Rhinitis. Davis GA, Rudy AC, Archer SM, Wermeling DP, McNamara PJ. Pharmacotherapy 2004; 24 (1) 26-32

Intranasal Delivery of recombinant human parathyroid hormone hPTH 1-34, teripartitide in rats. Agu R, Valiveti S, earles DC, Klausner M, Hayden PJ, Wermeling DP, Stinchcomb AL. Endocrine Research 2004; 30 (3), 455-467

"Pharmacokinetics of Butorphanol Tartrate Administered from Single-Dose Intranasal Sprayer", Davis GA, Rudy AC, Archer SM, Wermeling DP, *American Journal of Health-Systems Pharmacists* 2004;61:261-266

"Effect of Fluticasone Propionate Nasal Spray on Bioavailability of Intranasal Hydromorphone Hydrochloride in Patients with Allergic Rhinitis", Davis GA, Rudy AC, Archer SM, Wermeling DP, McNamara PJ, *Pharmacotherapy* 2004;24(1):26-32

"Pharmacokinetics and Pharmacodynamics of Intrathecal Ziconotide in Chronic Pain Patients", Wermeling DP, Drass M, Ellis D, Mayo M, McGuire D, O'Connell D, Hale V, Chao S, *The Journal of Clinical Pharmacology* 2003;43:624-636

"**Hydromorphone Transfer Into Breast Milk After Intranasal Administration"**, Edwards JE, Rudy AC, Wermeling DP, Desai N, McNamara PJ, *Pharmacotherapy* 2003;23(2):153-158

"Pharmacokinetics and Bioavailability of Single-Dose Intranasal Hydromorphone Hydrochloride in Healthy Volunteers", Coda BA, Rudy AC, Archer SM, Wermeling DP, *Anesthesia and Analgesia* 2003;97:117-123

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Evaluation of Drug Interactions
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Grant Activity

Funded Grants

ACCP Frontiers Award – "fMRI Imaged Neuroactivation and Craving in Alcoholics is Modulated by Ondansetron". American College of Clinical Pharmacy, $ 30,000, August 2007. Role: Principal Investigator.

NIH MO1RR02602 – Priority Score 150 – Alcohol Related fMRI Imaged Neuroactivation and Craving: Part A Imaging Validation; Part B Medication Administration. October 2007, Role: Principal Investigator.

NIH – R41HD055009-01, A Device Containing Immobilized Chelator to Remove Aluminum in TPN Solutions. October 2007, 2.5% effort, Role: Subinvestigator

NIH 1R41AA016500-01, Priority Score 161, Nasal Delivery of Naltrexone for the Treatment of Alcoholism: Role: Principal Investigator 10% effort. National Institute on Alcoholism and Alcohol Abuse, $ 100,000, June 2006.

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The Effects of Intranasal Corticotropin Releasing Hormone on Cortical and Subcortical Information Processing. PI Royce Lee, M.D. $ 1000 per year for 2 years. Role – Co-Investigator on grant from Brain Foundation and subcontract from University of Illinois Chicago. April 2006.

A Pilot Study of the Effect of Intranasal Corticotropin-Releasing Hormone on Emotion Processing in Remitted Depression. PI: Royce Lee, M.D. $ 30,000 over 2 years. Role – Co-investigator $ 3000/yr. NARSAD Foundation and University of Illinois subcontract. April 2006

Microneedle Assisted Naltrexone Hydrochloride Transdermal Delivery for the Treatment of Addictions. Role: Principal Investigator. NIH GCRC and UK Internal Competition. Pilot Research Project $29,500. April 2006

An Open Label Study Asssessing the Pharmacokinetics and Pharmacodynamics of Cangrelor Bolus Plus Infusion in Healthy Volunteers, The Medicines Company. Role: Co-investigator, $ 367,618. 2005.

Nasal Drug Delivery Development. Intranasal Technology, Inc. $ 18,000/yr. 2004

A Double Blind, Randomized, Placebo-Controlled, Crossover Study to Investigate the Safety, Tolerability and Pharmacokinetics of Single Oral Escalating Doses of GW572016 Ditosylate Monohydrate in Healthy Volunteers, Glaxo EFG10001(Co-Principal Investigator)
$379,970 1999

A Double Blind, Randomized, Placebo-Controlled, Parallel Study to Investigate the Safety, Tolerability and Pharmacokinetics of Multiple Oral Doses of GW572016 in Healthy Volunteers, Glaxo EFG10002 (Co-Principal Investigator)
$671,627 2000

ITI Infrastructure, Project #4 (DPEU). Inhalation Technology, Inc. (Principal Investigator)
$2,177,587 2000-1

A Single-Dose, Open-Label, Three Way Crossover, Randomized, Pilot Bioavailability Study of Lorazepam Comparing Intranasal Administration to Intravenous and Intramuscular Administration in Healthy Human Volunteers, Inhalation Technology, Inc. (Principal Investigator)
$116,174 2000

A Single and Multiple Dose Pharmacokinetic Study of 2.0 mg Intranasal Hydromorphone Hydrochloride in Healthy Volunteers, Inhalation Technology, Inc. (Principal Investigator)
$160,896 1998

Absolute Bioavailability of Intranasal Hydromorphone HC1 in Patients with Rhinitis and Rhinitis Treated with Oxymetazoline, Inhalation Technology, Inc. (Sub-Principal Investigator)
$118,454 1999

A Single-Dose Milk Transfer Study of Hydromorphone Hydrochloride Following Intranasal Administration in Healthy Human Volunteers, Inhalation Technology, Inc. (Sub-Principal Investigator)
$55,633 1999

A Pharmacokinetic, Bioavailability and Safety Study of 1.0mg Hydromorphone Hydrochloride Following Intranasal Administration and Intravenous Administration in Children and Adolescents with Existing Central Venous Access Catheters, Inhalation Technology, Inc., (Sub-Principal Investigator)
$74,374 1998

Absolute Bioavailability of Intranasal Hydromorphone HC1 in Patients with Perennial or Seasonal Allergic Rhinitis and with Perennial or Seasonal Allergic Rhinitis Treated with Flonase, Inhalation Technology, Inc., (Sub-Principal Investigator)
$81,236 2000

A Single and Multiple Dose Pharmacokinetic Study of 2.0mg Intranasal Hydromorphone Hydrochloride in Healthy Volunteers. Inhalation Technology, Inc. (Principal Investigator), 2000
$146,381

A Single Dose, Open Label, Three Way Crossover Bioavailability Study of 1.0 and 2.0 mg Intranasal hydromorphone HC1 in Healthy Volunteers. Inhalation Technology Inc. (Principal Investigator), 1999
$142,173

Open-Label Extension Study of Continuous Subcutaneous Infusion of Sufentanil Citrate for the Treatment of Chronic Pain. Pacific Research Assoc. (Principal Investigator), 1999

$99,918

Application to FDA for Notice of Suitability. Inhalation Technology, Inc. (Principal Investigator), 1999
$49,832

A Single Blind, Open-Label, Three Way Crossover, Randomized Pilot Bioavailability of Hydromorphone. Inhalation Technology, Inc. (Principal Investigator), 1999
$56,283

ITI-Project #3 Nasal Spray (DPEU). Inhalation Technology, Inc. (Principal Investigator), 1999
$914,201

Continuous Epidural Infusion of Ziconotide in Patients with Severe Chronic Pain: Open Label, Safety and Feasibility Study. Elan Pharm./Clinimetrics (Principal Investigator), 1999
$76,802

A Single-Dose, Open-Label, Three Way, Incomplete Block Crossover, Randomized, Pilot Study of Butorphanol Tartrate Comparing Intranasal Administration via Multi-Dose Spray pump Versus Single-Dose Sprayer in Healthy Human Volunteers. Inhalation Technology, Inc. (Principal Investigator), 1999
$79,931

A Single Blind, Open-Label, Three-Way Crossover Pilot Bioavailability Study of Hydromorphone HCL Comparing IN to IV and IM Administration in Healthy Human Volunteers. Inhalation Technology, Inc. (Principal Investigator), 1998
$56,283

Open-Label Dose-Filtration Study of Continuous Infusion of Sufentanil Citrate for the Treatment of Chronic Pain. Durect Corp. (Principal Investigator), 1998
$38,054

A Phase II Pilot Study of Ziconotide (SNX-111) Administered by Bolus Epidural Injection in Patients with Chronic Pain. Neurex/Elan Pharmaceuticals (Principal Investigator), 1998
$116,713

A Single Dose, Open Label, Three-Way Crossover, Randomized Pilot Bioavailability Study of Ondansetron, Hydrochloride Comparing Intranasal Aqueous and Gel Formulations to Intravenous Administration in Healthy Human Volunteers. Glaxo-Wellcome (Principal Investigator), 1998
$50,000

Alza E-Trans (Fentanyl) Protocol C-94-057. Paraxel (Principal Investigator), 1998
$17,800

A Prospective, Randomized Single-Blind Crossover Comparison Study of the Safety and Efficacy of Apothecon-Warfarin and DuPont-Warfarin in the Treatment of Patients with Atrial Fibrillation. Apothecon/UHC (Sub-Investigator), 1998
$75,045.47

Single-Site, Phase II, Open-Labeled, Rising Dose, Feasibility, Safety & Efficacy Study of SNX-111 Administered Intrathecally in Bolus Doses for Chronic Pain. Neurex (Principal Investigator), 1998
$136,754

An Open-Label, Long-Term Safety and Tolerability Study of Ziconotide® Administered Intrathecally to Patients with Chronic, Severe Pain. Elan Pharmaceuticals (Principal Investigator), 1998
$117,200

Multidisciplinary Clinical Research Training Program. National Institutes of Health (Sub-Investigator)
$1,080,000 (5 yr. budget – approx. $216,000 each year) submitted

A Four-Way Crossover, Dose Study of Flunisolide Administered Through Intravenous Injection, Oral Solution, and Oral Inhalation System (AEROBID) With and Without the Spacer (AEROCHAMBER) in Normal Healthy Male or Female Volunteers. Forest Laboratories(Principal Investigator, 1997)
$148,000

A Double-Blind, Parallel Group, Placebo-Controlled Study of Intravenous Kytril (Granisetron Hydrochloride) in the Treatment of Post-Operative Nausea and Vomiting in Patients Undergoing Elective Surgery with General Anesthesia. Smith-Kline Laboratories (Principal Investigator), 1996-1997
$20,000

A Multicenter, Phase II, Placebo-Controlled Pilot Study of SNX-111 Administered Intrathecally to Patients with Acute Postoperative Pain. Neurex (Co-Principal Investigator)
$36,000

The Effects of Renal Dysfunction on the Pharmacokinetics and Pharmacodynamics of Suramin in Cancer Patients. Parke-Davis Laboratories (Co-Principal Investigator)
$19,000

Investigation of the Influence of Topical Application of Glycolic Acid on the Percutaneous Penetration of Model Penetrants Through Human Skin in Vivo. Hilltop Research (Co-Principal Investigator)
$27,120

A Double-Blind, Placebo Controlled Trial of Metrifonate in Patients with Probable Alzheimer's Disease. Bayer, Inc. (Principal Investigator)
$152,400

An Open Label Extension Trial of Metrifonate in Patients with Probable Alzheimer's Disease. Bayer, Inc. (Co-Investigator)

$98,400

A Phase I/II Open Label, Rising Dose, Safety and Feasibility Study of SNX-111 Administered Intrathecally to Patients With Intractable Chronic Pain. Neurex (Co-Principal Investigator)
$33,500

A Trial of Recombinant Methionyl Human Brain Derived Neurotrophic Factor Given By Daily SQ Injection to Patients With Amyotrophic Lateral Sclerosis. Amgen (Co-Investigator)
$318,500

Multicenter, Double-Blind, Randomized, Placebo-Controlled, Dose-Finding, Safety and Tolerability Trial of R-IGF-1 in Patients With Acute Kidney Failure. Chiron (Co-Investigator)
$117,400

Double-Blind, Randomized, Placebo-Controlled, Parallel Group Trial of the Efficacy and Safety of Enlimomab Compared to Placebo Administered Within 6 Hours of Onset of Stroke Symptoms for Treatment of Acute Ischemic Stroke. Boehringer-Ingelheim (Co-Investigator)
$109,200

Cervene Modification of Outcome in Patients with Acute Ischemic Stroke: a Double-Blind, Randomized, Placebo-Controlled, Parallel Group, Dose Comparison Study by 24 Hour Infusion. Baker-Norton Pharmaceuticals (Co-Investigator)
$86,400

A controlled pilot study of 1,25(OH)D-3 (calcitriol) in the treatment of Alzheimer's Disease. NIH Program Project Grant - Specific Aim 2 (Co-Investigator)
Salary savings, 7.5% FTE (approx. $9,000/yr)

A Double-Blind, Placebo-Controlled Trial of Anti-Tumor Necrosis Factor in Patients with Severe Sepsis. Bayer (Co-Investigator)
$158,000

A Multi-Center, Pharmacokinetic and Pharmacodynamic Study of Dofetilide in Subjects With Stable Atrial Fibrillation (AF) and Reduced Left Ventricular Ejection Fraction, Pfizer (Co-Investigator)
$128,931

A Double-Blind, Randomized, Placebo-Controlled, Dose-Response, Study of Inhaled Nitric Oxide 9OHM-11771) in the Treatment of Acute Respiratory Distress Syndrome (ARDS) Ohmeda (Co-Investigator)
$175,240

A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of Intravenous Ondansetron for the Treatment of Postoperative Emesis in Pediatric Patients Undergoing Outpatient Surgery -Glaxo (Co-Investigator)
$30,000

An Open-Label Study of the Pharmacokinetics of Venlafaxine in Extensive and Poor Metabolizers of Dextromethorphan-Phase I Phenotype Study Wyeth-Ayerst (Co-Investigator)
$144,888

A Double-Blind Comparison of Sertindole and Haldol^{R}: An Assessment of the Chronic Safety, Efficacy, Quality of Life and Relapse in Stable Schizophrenic Patients (M93-132) Outpatient-Abbott Labs (Co-Investigator)
$174,019

A Double-Blind, Placebo-Controlled, Dose-Response Comparison of the Safety and Efficacy of Three Doses of Sertindole and Three Doses of Haldol^{R} in Schizophrenic Patients (M93-113) Inpatient Abbott Labs (Co-Investigator)
$106,192

Tricyclic Versus Serotonin Specific Reuptake Inhibitor Anti-Depressant in Low Back Pain, Pain Care Inc. (Co-Investigator)
$12,243

A Trial of Recombinant Methionyl Human Brain-Derived Neurotrophic Factor (f-tHuBDNF) Given By Daily Subcutaneous Injection to Patients with Amyotrophic Lateral Sclerosis (ALS) Amgen (Co-Investigator)
$136,500

Phase I Pilot Study Evaluating the Effect of Study-State CP- 99219 On the Pharmacokinetics of Theophylline in Healthy Male Subjects Pfizer (Co-Investigator)
$77,113

A Randomized, Double-Blind, Multi-Center Trial Comparing 7 Days of Oral Therapy With CP-99219 (100 mg or 200 mg daily) or Ciprofloxacin Hydrochloride (500 mg daily) for the Treatment of Uncomplicated Urinary Tract Infections Pfizer (Principal Investigator)
$35,973

Erythromycin Citrate: Bioequivalency Study-Baxter Healthcare Corporation (Principal Investigator)
$110,664

Randomized, Placebo-Controlled Trial of E5 Antiendotoxin Monoclonal Antibody in Patients With Severe Sepsis Pfizer (Co-Investigator)
$55,000

A Placebo-Controlled Study to Determine the Effects of 500mg, 1000mg and 2000mg Citicoline in Ischemic Stroke Patients Parexel (Co-Investigator) $83,460

The Safety and Efficacy of Tiagabine HCL Monotherapy in the Treatment for Partial Seizures: High Dose Versus Low Dose Abbott (Co-Investigator)
$90,809

A Double-Blind, Placebo-Controlled, Dose Finding Study to Evaluate the Safety and Efficacy of Three Different Doses of Metrifonate (BAY A 9826) in Patients with Probable Alzheimer's Disease Miles (Co-Investigator)
$221,000

Prospective, Double-Blind, Placebo-Controlled, Randomized, Multi-Center, North American Study of the Safety and Efficacy of Murine Monoclonal Antibody to Tumor Necrosis Factor (TNFMAb) for the Treatment of Patients With Septic Shock Miles (Co-Investigator)
$162,073

A Randomized, Double-Blind, Placebo-Controlled Study of Intravenous Ondansetron Versus Droperidol For the Prevention of Post-Operative Nausea and Vomiting In Outpatient Surgery. Glaxo (Principal Investigator)
$75,000

A Phase III Study of r-metHuG-CSF in the Treatment of Severe Community Acquired Pneumonia (CAP) Amgen (Co-Investigator)
$78,750

A Randomized, Double-Blind, Placebo-Controlled Trial Testing the Efficacy of Tirilazad Mesylate in Patients With Acute Ischemic Stroke (RANTTAS) (The Upjohn Company) NIH (Co-Investigator)
$75,000

A Double-Blind, Randomized, Multi-Center Study of the Safety and Recovery Profiles of Tracrium, Norcuron, and Pavulon in Intensive Care Patients Who Require Neuromuscular Blocking Agents to Facilitate Mechanical Ventilation. Burroughs Wellcome (Co-Investigator)
$46,803

Phase I Safety and Tolerance Study of IP-AD-32 in Patients with Refractory Cancer Confined to the Peritoneal Cavity. Theradex (Co-Investigator)
$24,155

A Double-Blind, Placebo-Controlled, Randomized, Single-Center Study of the Safety, Tolerability, and Pharmacokinetics of Metrifonate. Miles (Co-Principal Investigator)
$352,898

A Phase II/III Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging, Safety and Efficacy Study of Recombinant Human Ciliary Neurotrophic Factor. Regeneron (Co-Investigator)
$107,100

Open-Label, Multiple-Dose, Pharmacokinetic/Pharmacodynamic Study of Dirithromycin and Oral Contraceptives (On - 7/7/7/28). Lilly Research Laboratories (Principal Investigator)
$111,460

A Double-Blind, Placebo-Controlled, Study to Determine Whether Procrit Can Reduce Peri-Operative Transfusion Requirements In Subjects Undergoing Major Orthopedic Surgery. R. W. Johnson Research Institute (Co-Investigator)
$89,031

A Study to Evaluate the Safety and Efficacy of Human r-IL1ra in Increasing Survival in Patients With Severe Sepsis. Synergen (Co-Investigator)
$68,250

Induction and Maintenance of General Anesthesia: An Economic Evaluation of Propofol and Thiopental/Isoflurane in Patients Undergoing Elective Intra-Abdominal Surgery. Health Economics Research (Principal Investigator)
$181,480

A Placebo-Controlled Trial to Evaluate the Safety, Tolerability, and Potential Efficacy of Initiating IV Administration of CGS-19755 to Serious Head Trauma Patients Prior to Surgery. Ciba-Geigy (Co-Investigator)
$98,000

A Multi-Center Phase I Evaluation of AD-32 Administered by Intravesical Instillation in Patients with Superficial Transitional Cell Carcinoma of the Urinary Bladder. Anthra Pharmaceuticals (Co-Investigator)
$18,192

The Safety of Intravenous Valproate Abbott Laboratories (Co-Investigator)
$7,182

The Effects of Subcutaneous r-HuEPO in Patients with Chronic Lymphocytic Leukemia R.W. Johnson Pharmaceuticals Research Institute (Co-Investigator) $30,000

An Open Study to Determine the Safety and Efficacy of Procrit Sterile Solution in Correcting Anemia in Renal Transplant Patients with Chronic Graft Dysfunction, R.W. Johnson Pharmaceuticals Research Institute (Co-Investigator)
$36,070

A One Year Multi-Center Double Blind Comparison of the Effects of Once Daily Dosing with Three Dose Levels of SKF 105657 or Placebo in the Treatment of Symptomatic Benign Prostatic Hyperplasia with Six Month Untreated Follow-Up SmithKline Beecham (Co-Investigator)
$111,082

Dose Tolerance of DSPC Liposome in Healthy Volunteers The Liposome Company (Principal Investigator)
$162,389

A Controlled Trial of Intravenous Plus Oral RS-87476 in Acute Non-Hemorrhagic Cerebral Infarction Syntex Research (Co-Investigator) $30,000

Investigation of Intravenous Infusion Monitoring System: Site Check IMED Corporation (Co-Investigator)
$14,592

A Study to Evaluate the Safety and Efficacy of Human Recombinant Interleukin-1 Receptor Antagonist (IL-1RA) in the Treatment of Sepsis Syndrome Synergen, Inc. (Co-Investigator)
$153,000

A Double-Blind Comparison of the Efficacy of a Two-Dose Regimen of Oral Granisetron (1 mg twice, 2 mg once) in Preventing Active Nausea and Emesis in Patients Receiving Moderate Emetogenic Chemotherapy SmithKline Beecham (Co-Investigator)
$61,920

Kinetics of Edatrexate and Its Metabolites after Single 40 and 80 mg/m^2 Intravenous Doses in Cancer Patients with Varying Degrees of Renal Insufficiency Ciba-Geigy (Co-Investigator)
$97,750

Measurement of Muscle Strength and Abilities to Perform Activities of Daily Living in Patients with Amyotrophic Sclerosis Regeneron Pharmaceuticals (Co-Investigator)
$20,000

A Relative Bioavailability Study of RO 24-7429 (TAT Antagonist) Tablets (With and Without Food) vs. Oral Solution (Fasting) in Normal Volunteers Hoffman-LaRoche (Principal Investigator)
$72,487

Acute Dose Tolerance and Pharmacokinetics of Oral 1045U85/HCL in Healthy Male Volunteers Burroughs Wellcome (Co-Investigator)$237,754

Evaluation of NIH Implementation of Section 491 of the Public Health Services Act: A Program of Protection for Research Subjects National Institute of Health (Co-Investigator)
$765,296 - not funded

Evaluation of Gastric pH Control in Head Trauma Patients by Continuous IV Infusion of Cimetidine SmithKline Beecham - (Co-Investigator)
$23,161

Evaluation of Streptokinase Infusion Kit for the Emergency Room Delivery of Thrombolytic Therapy Baxter Healthcare Corporation - (Co-Investigator)
$48,000

Investigation of Intravenous Infusion Monitoring System: Gemini IMED Corporation - (Co-Investigator)
$18,958 Part A, $12,500 Part B

Transurethral Resection of Prostatic Tissue Using an Endoscopic Ultrasonic Surgical Aspirator System Valleylab, Inc. (Co-Investigator)
$204,286

Pharmacokinetic Analysis of Lidocaine Administered by the Baxter Infusor Baxter Healthcare Corporation (Co-Investigator)

$26,059

MK 787/791 vs. Ampicillin Plus Clindamycin plus Gentamicin in the Treatment of Serious Gynecological and Lower Abdominal Infections in Female Patients Merck Sharp & Dohme Research Laboratories (Co-Investigator)
$112,500

IRB Equitable Selection Survey ARENA (Co-Investigator)
$800

Single Oral Dose Pharmacokinetic and Pharmacodynamic Comparison of S-Atenolol and Racemic Atenolol (Termorin) in Healthy Adults Sepracor, Inc. (Co-Investigator)
$75,000

Pivotal Study of Human MAB-T88 in Patients with Gram-Negative Sepsis. Cetus Corporation (Co-Investigator)
$70,000

A Study to Assess the Effects of Chronic Oral Carvedilol on the Steady-State Pharmacokinetics of Oral Digoxin in Patients with Mild to Moderate Hypertension. SmithKline Beecham Pharmaceuticals (Principal Investigator)
$83,000

Double-Blind, Placebo-Controlled Study of the Effect of Ceftizoxime Sodium in the Management of Patients with Preterm, Premature Rupture of Membranes. Fujisawa Pharmaceutical Company (Co-Investigator)
$77,000

A Randomized Multi-Center Study of a Single Dose Oral Fluconazole Tablet Compared with Seven Days of Miconazole Vaginal Cream in the Treatment of Acute Candidal Vaginitis in Women 18-65 Years of Age. Pfizer Pharmaceuticals (Principal Investigator)
$35,000

A Randomized Multi-Center Study of a Single Dose Oral Fluconazole Tablet Compared with Seven Days of Clotrimazole Vaginal Tablets in the Treatment of Acute Candidal Vaginitis in Women 18-65 Years of Age. Pfizer Pharmaceuticals (Principal Investigator)
$70,000

A Phase II Dose Finding Placebo Controlled Study of YM617 in Patients with Signs and Symptoms of Benign Prostatic Hyperplasia. Yamanouchi Pharmaceuticals (Co-Investigator)
$95,000

A Phase II Open-Label, Randomized Controlled Study of rhIGF-1 in Patients with Severe Head Injury. Genentech (Co-Investigator)
$199,000

The Comparison of Sulbactam/Ampicillin (Unasyn) and Ampicillin/Gentamicin in the Treatment of Chorioamnionitis. Pfizer (Co-Investigator)
$116,000

Double-Blind, Placebo-Controlled Pilot Study Evaluating Safety and Tolerability of Two Intravenous Bolus Doses of CGS-19755 in the Treatment of Patients with Acute Stroke. Ciba-Geigy (Co-Investigator)
$84,000

A Placebo Controlled, Double Blind, Crossover, Dose/Response Study of Oral Torsemide in Patients with Ascites Due to Cirrhosis. Boehringer Mannheim Pharmaceuticals (Principal Investigator)
$59,200

Acute Dose Tolerance, Pharmacokinetics, and Pharmacodynamics of Oral 349U85 in Healthy Male Volunteers. Burroughs Wellcome (Co-Investigator)
$270,000

Comparative Clinical Efficacy of Two Tablet Strengths of Deflazacort in the Treatment of Steroid Dependent Asthma. Merrell Dow Pharmaceutical (Co-Investigator)
$52,278

Long Term Safety and Efficacy Study of Deflazacort in Patients with Chronic Steroid Dependent Asthma. Merrell Dow Pharmaceutical (Co-Investigator)
$21,356

Comparative Safety and Efficacy of Clarithromycin and Suprax in the Treatment of Lower Respiratory Tract Infections. Abbott Laboratories (Co-Investigator)
$24,000

Unasyn - Pharmacy Surveillance Project. Pfizer Pharmaceuticals (Co-Investigator)
$275,000

A Double-Blind, Placebo Controlled Study to Determine the Safety of r-HuEPO and Whether r-HuEPO can Reduce the Postoperative Transfusion Requirements in Subjects Undergoing Orthopedic Surgery. R.W. Johnson Foundation (Co-Investigator)
$79,000

Assessment of Time to Study State After Multiple Dose Nefazodone in Extensive and Poor Metabolizers of Dextromethorphan. Bristol-Myers (Co-Investigator)
$150,000

Infusion Device for Lidocaine Administration. Baxter Laboratories (Co-Investigator)
$70,000

Evaluation of the Travenol Infusor/Patient Control Module for the Treatment of Postoperative Pain Travenol Laboratories (Co-Investigator)
$25,000

Evaluation of Stadol with the Travenol Infusor and Patient Control Module for Patient-controlled Analgesia. Bristol-Myers (Co-Investigator)
$12,500

An Evaluation of the Bioavailability of BW825C and Pseudoephedrine from 825C/Pseudoephedrine Combination Capsules and Syrup in Normal Male Volunteers. Burroughs Wellcome Company (Co-Investigator)
$52,108

A Randomized Comparative Trial of Morphine Administered by Patient-Controlled Analgesia vs. Intramuscular Injection for the Treatment of Pain in Postoperative Patients. Bard Medsystems (Principal Investigator)
$8,000

Multi-Institutional Study of Patient-Controlled Analgesia. Travenol Laboratories (Principal Investigator)
$100,050

A Comparative Study Of CGS-15849 vs. Its Components and Placebo on Intraocular Pressure in Normal Subjects. Ciba-Geigy (Co-Investigator)
$65,678

A Multiple Dose Placebo Double-Masked Comparative Tolerability Study of Diclofenac Sodium vs. Placebo in Normal Subjects. Ciba-Geigy (Co-Investigator)
$84,114

Other Creative Activity

National

"Advent IV Medication Delivery Systems Implementation Guide." A reference manual for pharmacists preparing small volume parenteral using a gravity-feed syringe system. Sponsored by Quest Medical.

"Patient-Controlled Analgesia Device Inservice." A VHS tape describing methods for pharmacy preparation, nurse monitoring and patient utilization of a novel PCA device. Sponsored by Baxter.

"Electronic Research Administration Binder." An asserted copyright computer program for research administration. 1998

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- Co-founder and consultant for a university based start-up specialty pharmaceutical and drug delivery company – 1996 - 1999

- Senior Vice President and Chief Operating Officer – 1999-2004
- Chief Scientist 2004 - 06
- Technology based on University of Kentucky research in nasal transmembrane delivery of pharmaceuticals to the systemic circulation
- From 1996-2003 ITI funded over $6 million into University of Kentucky research programs. The research funding supported major programs at UK and lead to scholarly productivity by faculty
- Patents have been submitted and issued to UK from this research
- ITI has licensed the technology from UK and is partnering with larger pharmaceutical companies for finance and marketing support
- ITI has moved initial operations in the University incubator facility to the UK Coldstream Research campus where a research and development and manufacturing plant has been constructed
- ITI was the first private company to receive equity and debt financing from the Commonwealth of Kentucky Economic Development Cabinet. Total investment was $3.5 million
- Inventions are currently in Phase 1-3 trials
- In July 2006 ITI closed a $ 39 million venture capital financing for clinical and basic research and physical plant expansion